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No. _____

Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1995

ALFRED BINGHAM,

Cross-Petitioner,

v.

MENTOR CORPORATION,

Cross-Respondent.

On Cross-Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Do the Medical Device Amendments to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.*, preempt state-law claims to recover for injuries caused by a defective medical device?

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CROSS-PETITION FOR A WRIT OF CERTIORARI

Alfred Bingham petitions for review of a ruling of the United States Court of Appeals for the Fifth Circuit concerning injuries that he received from Mentor Corporation's allegedly defective inflatable penile prosthesis. Specifically, the court of appeals held that cross-petitioner's state-law claims based on failure to warn were preempted; implied warranty claims based on failure to warn were preempted; and state deceptive trade practices claims based on failure to warn were preempted. Cross-petitioner seeks review of the ruling below on the claims that the court held were preempted.

The Fifth Circuit also held that cross-petitioner's claims based on the defective design of the medical device were not preempted. These claims were based on negligence, strict liability, implied warranty, and state deceptive trade practices. The holding below that these claims based on the design of the product are not preempted forms the basis of Mentor's petition for writ of certiorari docketed on February 27, 1996. *Mentor Corp. v. Bingham*, No. 95-1367.

OPINIONS BELOW

The opinion of the court of appeals is unpublished, and is reproduced in the appendix to the petition of Mentor (Pet. App.) at Appendix A (Pet. App. 1-3). The unreported opinion of the United States District Court for the Southern District of Texas is reproduced in the appendix to the petition at Appendix B (Pet. App. 4-22).

JURISDICTION

The judgment of the court of appeals was entered on January 5, 1996. Mentor Corporation's petition for writ of certiorari was docketed on February 27, 1996, No. 95-1367. This cross-petition is being filed within 90 days of the entry of judgment of the court of appeals. This Court has jurisdiction over the cross-petition under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

This case involves the preemption provision of the Medical Device Amendments of 1976 (MDA) to the Food, Drug and Cosmetic Act, 21 U.S.C § 360k. Also involved is the regulation of the Food and Drug Administration (FDA) interpreting the preemption statute, 21 C.F.R. § 808.1(d).

21 U.S.C. § 360k(a) provides in pertinent part:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. § 808.1(d) provides in pertinent part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

STATEMENT OF THE CASE

The question presented is essentially that presented in *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995), *cert. granted*, 116 S. Ct. 806 (Jan. 19, 1996) (Nos. 95-754, 95-886). The issues are also similar to those presented in *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3469 (Dec. 26, 1995) (Nos.

95-1037, 95-1214). In addition, the question presented is also essentially the same as that presented in two other cases pending before this Court on petitions for writs of certiorari: *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 194 (4th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3439 (U.S. Dec. 22, 1995) (No. 95-1010); and *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3439 (U.S. Dec. 26, 1995) (No. 95-1034). In light of this Court granting review in *Lohr*, as well as the already extensive briefing on the question presented, this cross-petition will be kept brief.

A. Factual and Procedural Background.

On October 20, 1989, Alfred Bingham was implanted with a Mentor Mark II inflatable penile prosthesis, a medical device designed to treat erectile impotence. The device was designed, manufactured, and sold by Mentor Corporation. In June of 1992 the device failed. Suit was filed on January 5, 1994, in U.S. District Court for the Southern District of Texas seeking recovery under various state-law causes of action including negligence, implied and express warranty, the Texas Deceptive Trade Practices Act, and products liability based on defects in design, marketing, and manufacturing. Jurisdiction in the district court was based upon diversity under 28 U.S.C. §§ 1332, 1441.

The MDA became effective on May 28, 1976. Before that date medical devices were essentially unregulated. The regulatory scheme set forth in the MDA provides for the classification of medical devices into three classes. 21 U.S.C. § 360c. The least dangerous devices were to be

classified as Class I devices and regulated by general controls. 21 U.S.C. § 360c(a)(1)(A). Class II devices were to have additional special controls, including performance standards. 21 U.S.C. § 360c(a)(1)(B). Class III devices encompass the most potentially dangerous devices, and to ensure safety and effectiveness, and to protect the American public, Class III devices were to be subject to premarket approval (PMA). 21 U.S.C. § 360c(a)(1)(C).

Most Class III devices, however, do not reach the market after undergoing the PMA process. Instead, there are exceptions to the general PMA rule. First, devices that are of the same model as a device that was already on the market prior to the effective date of the MDA, May 28, 1976, are not subject to premarket approval. These are so-called "grandfathered" devices. Second, devices that are "substantially equivalent" to devices marketed prior to May 28, 1976, can be marketed by filing with the FDA what is known as a 510(k) notification submission. 21 U.S.C. § 360(k).

All Class III devices will eventually have to undergo the PMA process and obtain approval. But even now, almost twenty years since the MDA took effect, many Class III devices remain on the market without having undergone the PMA process. The device involved in this case, the inflatable penile prosthesis, is a Class III device. 21 C.F.R. § 876.3350. It is undisputed that the device is a 510(k) device and has not undergone the PMA process. The FDA has specifically taken the position that a 510(k) determination of substantial equivalence "does not in any way denote official approval of the device." 21 C.F.R. § 807.97.

B. The District Court Proceedings.

Mentor Corporation raised nineteen affirmative defenses in its amended answer, including the complete preemption of all state-law claims. Mentor moved for summary judgment on June 29, 1994, based on the preemption defense. On March 21, 1995, the district court granted summary judgment in favor of Mentor on all claims.

C. The Court of Appeals' Opinion.

The Fifth Circuit, in a short *per curiam* opinion, followed the case of *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3469 (Dec. 26, 1995) (Nos. 95-1037, 95-1214). The Fifth Circuit disagreed with the district court that the 510(k) notification process constitutes a requirement that would preempt all of Mr. Bingham's claims. The court also refused to broadly hold that because there are some GMP's that would apply to the device, all of Mr. Bingham's claims would be preempted. Nevertheless, the court below held that claims based upon inadequate warnings or labeling would be preempted by the general controls, including GMP's.

REASONS FOR GRANTING THE WRIT

THE DECISION BELOW CONFLICTS WITH DECISIONS OF OTHER COURTS OF APPEALS ON AN IMPORTANT ISSUE OF FEDERAL LAW.

The extent to which a consumer can proceed with a claim for damages for injuries resulting from a defective medical device now depends upon the circuit. In the Ninth Circuit, none of Mr. Bingham's claims would be preempted. In a case involving Zyderm, the same Class III, PMA-approved product at issue in the Fifth Circuit case of *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993), the Ninth Circuit held that state common law is a law of general applicability and that the MDA does not preempt laws of general applicability. *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995). In the Ninth Circuit an individual retains all of his or her common law rights to sue for damages for an injury received from a medical device.

The Fifth Circuit mistakenly held that cross-petitioner's claims other than the design-related claims were preempted. In the first instance, the court below mistakenly held that the preemption statute encompasses state common law claims. The court failed to properly consider the language, structure, and purpose of the MDA. The Fifth Circuit's decision below is at odds with the Ninth Circuit's decision in *Kennedy* that the MDA does not preempt common law actions at all.

Second, the lower court refused to defer to the FDA interpretation that requires specific requirements relating to a specific device before preemption would apply. General controls, including general labeling regulations, are

not device specific. The lower court incorrectly held that general FDA requirements trigger preemption of claims. The warnings at issue in *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989), were device specific for tampons. *Moore*, 867 F.2d at 246. In contrast, the labeling and warnings at issue here were not device specific for penile prostheses.

In the Third Circuit the Mentor GFS inflatable penile prosthesis was also the product at issue in the *English* case. Although the product and manufacturer were the same, the analysis and result were different from that reached by the Fifth Circuit. The Third Circuit, in conflict with the Fifth Circuit, held that the 510(k) process was a requirement that preempted state law claims. *English*, 67 F.3d at 482. As a result, design-related claims are now preempted in the Third Circuit, even though the design in question is based upon the design of a product that was on the market prior to the adoption of the MDA in 1976. This is the subject of Mentor's petition for review, but the broader question of differing circuit results and analyses carries over to the other claims and therefore warrants review of the decision below in its entirety.

The circuit court decisions now run the spectrum from no preemption, to some preemption, to total preemption. There is now a mature circuit conflict in an area of great importance that warrants Supreme Court review.

CONCLUSION

By granting the petition for a writ of certiorari in the *Lohr* case, this Court has already determined that the issue of the scope of MDA preemption is ripe for review. Mr. Bingham has filed his cross-petition so that in the event the Court determines that an additional case is necessary to fully explore the issue, the Court will have the entire preemption controversy to decide, and not just the narrow issue of the preemption of design claims.

Alfred Bingham's cross-petition for a writ of certiorari should be granted.

Respectfully submitted,

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